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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/543,407	04/05/2000	Aaron P. White	920043.406	7308

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EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 03/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	Application N .	Applicant(s)
	09/543,407	WHITE ET AL.
	Examiner Vanessa L. Ford	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 December 2001.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-34, 41-44 and 48-53 is/are pending in the application.
- 4a) Of the above claim(s) 15-17, 22-24, 29- 31-33, 41-43, 48-50 and 52-53 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14, 18-21, 25-28, 34, 44 and 51 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-34, 41-44, 48-53 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2 and 11</u> . | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. Applicant's election without traverse of Group I, claims 1-34, 41-44 and 48-53 in Paper No. 13 filed on September 19, 2001 is acknowledged. Applicant's election of species A, *agfA* gene in Paper No. 15 filed on December 10, 2001. Claims 35-40, 45-47 and 54-55 have been cancelled. Claims 15-17, 22-24, 29- 31-33, 41-43, 48-50 and 52-53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 1-14, 18-21, 25-28, 34, 44 and 51 are being examined as they relate to the elected invention, a recombinant gene, species, *agfA* gene.

***Specification Objections***

2. The specification is objected to because of the following informalities: The specification recites "Salmonella", page 19, line 24 which should be italicized. The genus and species of an organism should be italicized. The specification should be reviewed for these informalities and correction is required.

3. The specification is objected to because of the use of worldwide web addresses on page 36, lines 11, 12-13 and 13-14. The worldwide web address can be readily changed and therefore, may not be available to the public. The specification should be reviewed for worldwide web addresses and the web address must be deleted from the specification.

***Claim Objections***

4. Claim 5 is objected to because of the following informalities: Claim 5 recites "Enerobacteriaceae" which appears to be a typographical error. Claim 5 should recite "Enterobacteriaceae". The applicant is asked to review the claims for typographical errors and correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18, 25, 34, 44 and 52 are rejected to because they fail to particularly point out the claimed invention. These claims are drawn to non-elected species. The Applicant should amend the claims so that they do not include non-elected species.
6. Claims 3-8, 19-21 and 26-28 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "capable of". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "capable" cannot be ascertained. Clarification as to the meaning of this term is required.

7. Claim 44 is rejected because it fails to particularly point out the claimed invention. Claim 44 is unclear because it depends from claims 38-40 which recite a

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method. The elected invention is drawn to a product, a recombinant gene. Clarification is required.

8. Claim 51 is rejected because it fails to particularly point out the claimed invention. Claim 51 is unclear because it depends from claims 45-47 which recite a method. The elected invention is drawn to a product, a recombinant gene. Clarification is required.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-14, 19-21 and 26-28 are rejected under 35 U.S.C. 102(b) as anticipated by Kay et al (*WO 94/25598, published November 10, 1994*).

Claims 1-14, 19-21 and 26-28 are drawn to a recombinant *agfA* gene in which a segment of the gene has been replaced by a segment of a foreign DNA sequence, that foreign sequence encoding a foreign epitope or antigen.

Kay et al teach *agfA* genes from *Salmonella* that have been engineered so that they contain foreign antigens or epitopes. Kay et al teach that the foreign antigen or epitope is foreign to the *Salmonella* and the host cell. Kay et al teach that *E. coli* can be used to express the one or more *Salmonella agfA* genes (page 40). Kay et al teach

that *Shigella* or other Enterobacteriaceae can be used in this invention (page 6). Kay et al teach that the bacterial host cell that comprises the recombinant gene is able to express a stable *Salmonella AgfA* fimbrin protein fused to one or more foreign antigens. Kay et al teach that both the *Salmonella*-based antigen and the foreign antigen are able to elicit a response from the immune system of the host animal yielding a multipurpose composition/immunogen (page 23). It would be inherent in the teachings of the prior art that the recombinant *agfA* gene would replace the native *agfA* gene.

Since the Office does not have the facilities for examining and comparing applicant's recombinant gene with the recombinant gene of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the recombinant gene of the prior art does not possess the same material structural and functional characteristics of the claimed recombinant gene). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Note: The Examiner is examining claims 44 and 51 as they related to the elected invention, a recombinant gene, species *agfA*.

10. Claims 18, 25, 34, 44 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kay et al (*WO 94/25598, published November 10, 1994*) in view of Collinson et al (*Journal of Bacteriology, February 1996, p. 662-667*).

Claims 18, 25, 34, 44 and 51 are drawn to a recombinant gene of claims 1-14 wherein the recombinant gene is an Enterobacteriaceae homologue of the *agfA* gene.

Kay et al teach *agfA* genes from *Salmonella* that have been engineered so that they contain foreign antigens or epitopes. Kay et al teach that the foreign antigen or epitope is foreign to the *Salmonella* and the host cell. Kay et al teach that *E. coli* can be used to express the one or more *Salmonella agfA* genes (page 22). Kay et al teach that *Shigella* or other Enterobacteriaceae can be used in this invention (page 6). Kay et al teach that the bacterial host cell that comprises the recombinant gene is able to express a stable *Salmonella AgfA* fimbrin protein fused to one or more foreign antigens. Kay et al teach that ~~both~~ both the *Salmonella*-based antigen and the foreign antigen are

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able to elicit a response from the immune system of the host animal yielding a multipurpose composition/immunogen (page 23).

Kay et al do not teach homologues of the *agfA* gene.

Collinson et al teach that *Salmonella enteritidis* produces thin, aggregative fimbriae named Sef17 which are composed of polymerized AgfA fimbrin proteins. Collinson et al teach that the *agfA* gene encodes the AgfA fimbrin which is similar to the *Escherichia coli* curli structural protein, CsgA (see the Abstract). Collinson et al teach that the major structural genes *agfA* and *csgA* are homologous (page 666).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace the recombinant *agfA* gene as taught by Kay et al with as *agfA* gene homolog such as *csgA* because Collinson et al teach that the *csgA* gene of *E. coli* is homologous to the *S. enteritidis* gene and therefore would be able to express a recombinant protein. It would be expected barring evidence to the contrary that the substitution of *agfA* gene with *csgA* gene would produce a stable recombinant fimbrin protein because of its high degree of similarity to the *S. enteritidis agfA* gene, the genetic organization and the common ancestry (see the Abstract).

#### ***Pertinent Prior Art***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure (*Hedegaard et al, Gene, 1989, p. 115-124, Cardenas et al, Vaccine, Vol. 11, Issue 2, 1993, Doran et al, U.S. Patent No. 5635617, published 1997*

*and Pallesen et al, Fimbriae: Adhesion, Genetics Biogenesis and Vaccines, Klemm (ed.), 1994, CRC Press, Boca Raton).*

### **Status of Claims**

12. No claims are allowed.

### **Conclusion**

13. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
February 21, 2002

  
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